



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,082	07/10/2000	CHENICHERI H. NAIR	5-00	5840

23713 7590 06/27/2002

GREENLEE WINNER AND SULLIVAN P C
5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/27/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/463,082	NAIR ET AL.	
	Examin r	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 31-63 are pending. The Amendment filed 5/13/02, cancelled claims 1-30.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed 5/13/02 (Paper No. 10) to the rejection of claims 1-30 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

The Applicant's arguments and amendment filed 5/13/02 (Paper No. 10) to the rejection of claims 1-7, 11-12, 14-15, 17-18, 20 and 22-27 made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive-in-part.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-32, 41-42, 50, 61-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Applicant argues, regarding the term "some", "this term is perfectly clear". This argument is not persuasive. Quantitatively, what is some? One of ordinary skill would not know how much "some" is, and this term is not defined in the specification. Accordingly, claims 31, 32, 41, 50 are rejected.

Art Unit: 1617

(ii) The term "fibrin-containing source" in claim 32 is vague and indefinite, as it is not clear what is encompassed by this term. What are fibrin containing sources? The specification does not further define this phrase and one of ordinary skill would not be apprised of what "sources" are being referred to.

(iii) Applicant argues, regarding the term "stable", "Stable as used in the claim is intended to mean 'non-reactive' as would be readily understood by one of ordinary skill in the art". This argument is not persuasive. The term stable is relative, as there is no means to compare what stable or unstable means when recited in the context of the claims and specification. Accordingly claim 42 is rejected.

(iv) The term "increases" in claims 61-63 is a relative term which renders the claims indefinite. The term "increases" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

103 Rejection Maintained

The rejection of newly added claims 31-63 under 35 U.S.C. 103(a) as being unpatentable over Burch et al. (Nuc. Med. Communications) in view of Chignier et al. (Biomat.) in further view of Watson et al. (WO 93/15768) and Senden et al. (Jn. Of Nuc. Med.) is MAINTAINED for the reasons set forth in the Office Action mailed 1/11/02, Paper No. 8, and those found below.

Applicant argues, "The Burch reference does not teach or suggest the use of technegas in aqueous settings nor does it teach or suggest its use in circulation". This argument is not persuasive. First, the Examiner respectfully points out that the technetium-99m compounds are

Art Unit: 1617

in aqueous aerosols (see pg. 866, second paragraph). Second, the Examiner respectfully points out that this argument is not commensurate in scope with the independent claims, as the independent claims place no limitations for the composition's use in the circulation.

Applicant argues, regarding Chignier, "It appears that the carbon-containing material of this reference are glassy or fibrous, rather than small discrete particles. . . The present invention as claimed does not relate to implanted devices or other materials. This reference appears to teach that the surfaces should be highly smooth and inert. This teaching is dramatically different from a method which requires discrete particles to be introduced into circulation". This argument is not persuasive. First, the Examiner respectfully points out that the reference was not relied upon for its teachings of small discrete particles or implanted devices, but was relied upon for teaching that fibrin adheres to carbon particles. Second, the Examiner respectfully points out that this argument is not commensurate in scope, as the independent claims place no limitations for the composition's use in the circulation.

Applicant argues, regarding Senden, "There is no teaching or suggestion of the dispersed nature of discrete particles in aqueous solution". This argument is not persuasive, as Senden was relied upon for teaching that technegas contains discrete radio-labeled fullerenes, and not for teaching the dispersion of particles in an aqueous solution.

Applicant argues, regarding Watson, "This reference provides no teaching or suggestion of how to disperse the carbon species in solution. The dispersed nature of the particles of the present invention is crucial to the usefulness of the particles in fibrin imaging". This argument is not persuasive, as Watson was relied upon for teaching carbon particles as diagnostic and therapeutic agents, and not for teaching the dispersion of particles in aqueous solution.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues, "The key aspect missing from the cited references is the dispersed nature and discrete particles of the labeled carbon". This argument is not persuasive. Again, the Examiner respectfully directs the Application to Burch et al., wherein the reference teaches that it is known to place technetium-99m compounds in aqueous carriers.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data on pages 14-27 of the specification have been considered but not found persuasive because the data merely demonstrate the effectiveness of the instant composition to bind fibrin. This is seen to be an expected result based on the cited prior art.

Conclusion


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200